POLICY AND PROCEDURES

OFFICE OF NEW DRUGS

Classifying Resubmissions of Original NDAs, BLAs, and Efficacy Supplements in Response to Action Letters

Table of Contents

PURPOSE

- This MAPP describes how the Center for Drug Evaluation and Research (CDER) will classify resubmissions of original new drug applications (NDAs), biologics license applications (BLAs), and efficacy supplements, received in response to action letters, as Class 1 or Class 2 resubmissions.

BACKGROUND

- As referenced in the Prescription Drug User Fee Act of 1992 (PDUFA), the Food and Drug Administration (FDA) committed to certain user fee performance goals including the goal of reviewing and acting on an applicant's resubmission of an original NDA in 6 months or less. In the November 1997 letter to Congress regarding the reauthorization of PDUFA, the Secretary of Health and Human Services committed the FDA to recognizing two classes of resubmissions: Class 1 and Class 2. The classification of a resubmission is based on the information submitted by the applicant in response to an action letter. The two classes of resubmissions also have different performance goals — expressed as the percentage of resubmissions that will be reviewed and acted upon within a certain time period from the date the resubmission is received by CDER based on the fiscal year in which the resubmission is received. These goals are re-evaluated at each PDUFA reauthorization.

POLICY

- The review team and division director will determine the classification of the response, and a letter will be issued to the applicant acknowledging receipt of the resubmission within 14 calendar days stating the classification of and the due date for action on the resubmission.

- CDER will complete the review and act on Class 1 resubmissions within the time frames agreed to in conjunction with the reauthorization of PDUFA.

- CDER will complete the review and act on Class 2 resubmissions within the time frames agreed to in conjunction with the reauthorization of PDUFA.

- If CDER does not agree that the submission is a complete response addressing all deficiencies in the complete response letter, the applicant will be so informed, and the review clock will not start until a complete response is received.

- The Class 1 or Class 2 distinction does not pertain to resubmissions of nonefficacy supplements. Responses to these resubmissions will have an internal goal date that begins on the receipt date and does not exceed the length of the initial review cycle.

RESPONSIBILITIES AND PROCEDURES

The Review Team and Division Director will:

- Determine the classification of a resubmission.

- Complete the review and act on all Class 1 and Class 2 resubmissions within the time frames agreed to in conjunction with the reauthorization of PDUFA.

The Regulatory Project Management Staff will:

- Upon receipt of the resubmission from the applicant, consult with the review team and division director on the classification of the resubmission.

- Ensure that an *acknowledgment of receipt* letter is drafted for the resubmission, stating the classification of the resubmission and the review goal date. This letter should be issued to the applicant within 14 calendar days of receipt of the resubmission.

- Send the applicant the standard letter *acknowledgment of incomplete response to an action letter* if the division does not agree that the submission is a complete

response, and ensure that the entry in the application database is corrected to reflect this determination.

REFERENCES

- The Prescription Drug User Fee Act Web page at http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm

DEFINITIONS

- **Resubmission —** A submission to an NDA, BLA, or efficacy supplement that purports to answer all of the deficiencies that need to be addressed by the applicant before approval as set forth in a previous action letter.

  – **Class 1 Resubmission —** A resubmission that includes one or more of the following items:

    1. Final printed labeling
    2. Draft labeling
    3. Safety updates submitted in the same format, including tabulations, as the original safety submission with new data and changes highlighted (except when large amounts of new information, including important new adverse experiences, not previously reported with the product are presented in the resubmission)
    4. Stability updates to support provisional or final dating periods
    5. Commitments to perform mandatory postmarketing studies, including proposals for such studies
    6. Assay validation data
    7. Final release testing on the last 1-2 lots used to support approval
    8. A minor re-analysis of data previously submitted to the application (determined by the FDA as fitting the Class 1 category)
    9. Other minor clarifying information (determined by the FDA as fitting the Class 1 category)

– **Class 2 Resubmission —** A resubmission that includes any item not specified as a Class 1 item, including any item that would require a presentation to an advisory committee. A resubmission that requires a reinspection also would be a Class 2.

EFFECTIVE DATE

This MAPP is effective upon date of publication.